II. REMARKS

Upon entry of the amendment, claims 1 to 15, 19 to 30, 33 to 37 and 40 to 56 will be pending. A marked version of the claims showing the amendments is attached hereto as Exhibit A.

Applicants and Applicants' representatives gratefully acknowledge the attention to the application and helpful suggestions made by Examiner Lewis and Supervisory Examiner Wilson in the telephone interview held February 5, 2003.

A. Regarding the Amendments

Claims 1, 9, and 23 have been amended to more clearly indicate that an effective amount of β-cyclodextrin is used in the methods of the invention, and that said β-cyclodextrin reduces the risk of transmission of a sexually transmitted pathogen (claims 1 and 23) or reduces the risk of the subject becoming infected with a sexually transmitted the pathogen (claim 9). It is submitted that the claims as amended clarify that β-cyclodextrin (βCD), itself, is an active agent that, for example, reduces the risk of transmission of or infection with a sexually transmitted pathogen.

The amendments are supported, for example, at page 28, lines 25-31, which discloses that an "effective amount" of βCD can block infection of susceptible cells by a sexually transmitted pathogen such as free HIV, or cell-associated HIV present in a secretion, or by uptake of the pathogen due to binding to otherwise non-susceptible cells, which then transfer the sexually transmitted pathogen to susceptible cells; and at page 26, lines 18-20, which discloses that βCD can be formulated as a composition for use according to a method of the invention, provided the formulation "does not affect the activity of βCD, or, if it affects the activity of the βCD, does so in a predictable way such that an amount of βCD that is effective for reducing the risk of transmission of a sexually transmitted pathogen can be determined" (page 26, line 23, to page 27, line 3). As such, the amendments do not add new matter.

Claims 37 and 40 have been amended to more clearly indicate that a composition "consisting essentially of a β-cyclodextrin "optionally" can include "an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof". The amendment to claims 37 and 40 are supported by claim 37 as originally filed, and, for example, at page 26, line 17, to page 27, line 3, and, therefore, do not add new matter.

New claims 52 to 56 have been added. The new claims are based, in part, on originally filed claims 17, 18, 31, 32, 38 and 39, and, for example, at page 25, lines 1-7, and page 26, line 17, to page 27, line 3. As such, the new claims are supported by the specification, including the claims as originally filed, and do not add new matter.

B. Double Patenting Rejections

The provisional rejection of claims 1 to 15, 19 to 30, 33 to 37, and 40 to 51 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 4, 6 to 15, 19, 20, 22 to 30, 33 to 37, and 40 to 45 of the copending application U.S. Serial No. 09/801,393 ("the '393 Application") is respectfully traversed.

A Terminal Disclaimer, disclaiming any term of a patent issuing from the subject application that may extend beyond the term of a patent issuing from the '393 Application, is submitted herewith. Accordingly, it is respectfully requested that this provisional rejection of the claims be removed.

C. Prior Art Rejection

The rejection of claims 1 to 15, 19 to 30, 33 to 37, and 40 to 49 under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. (U.S. Pat. No. 6,068,851), in view of Baert et al. (WO 97/18839) and Sokal et al., (U.S. Pat. No. 5,819,742) is respectfully traversed.

It is stated in the Office Action (page 3, paragraph 10) that, while the claims recite the term "consisting essentially of", for purposes of prior art, the term is construed as "comprising" absent a clear indication in the specification as to the basic and novel characteristics of the claimed invention (citing to MPEP § 2111.03). As discussed in the Interview with the Examiner, however, the specification discloses that β-cyclodextrin (βCD) is active in preventing transmission of a sexually transmitted pathogen (see, for example, page 5, lines 6-23; page 8, lines 10-20; and page 25, lines 1-7; see, also, page 26, line 18, to page 27, line 3). Thus, the specification clearly discloses the basic and novel characteristics of the claimed methods and composition, i.e., that a βCD has activity in reducing the risk of transmission of or infection with a sexually transmitted pathogen. Accordingly, it is submitted that the claims should be considered in view of the term "consisting essentially of" meaning that a composition of the invention or useful in practicing a method of the invention contains a βCD as the active ingredient.

Prior to Applicant's disclosure, cyclodextrins, including βCDs, were used only as solubilizing agents or as carriers of pharmaceutically active compositions (see, for example, specification at page 5, lines 15-21). However, it was not known that βCDs, alone, have a pharmaceutical activity or, in particular, that a βCD can be used to reduce the risk of infection or transmission of a sexually transmitted disease. It is noted that the compositions of the invention optionally can include a contraceptive, an agent for treating a sexually transmitted disease, and/or a lubricant. It is submitted, however, that such additional agents "do not materially affect the basic and novel characteristics of the claimed invention" (see MPEP2111.03), i.e., the determination that βCD is active in reducing the transmission of or infection with a sexually transmitted pathogen, and, therefore, properly encompassed within the claimed compositions.

It is stated in the Office Action that Bergeron et al. describe compositions and methods for preventing the transmission of sexually transmitted pathogens through mucosae and/or skin, wherein the composition can act as a physical chemical or pharmacological barrier, and that the composition can include, for example, a viral inhibitor such as an HIV protease or reverse transcriptase inhibitor, which can be encapsulated in cyclodextrin. However, Bergeron et al. do not teach or suggest that a cyclodextrin, alone, has any activity, but only mention that a cyclodextrin can be used as a carrier or encapsulating material, for example, for encapsulating a viral inhibitor (column 4, lines 5-11).

Baert et al., which is combined with Bergeron et al., describe βCD, and indicate that a βCD can be combined with an active ingredient, for example, loviride, which is an anti-retroviral agent. However, Baert et al. also do not teach or suggest that a βCD is an "active agent" and, therefore, do not provide the teaching that is missing in the Bergeron et al. reference, i.e., that a βCD can "reduce the risk" of transmission of a sexually transmitted pathogen or of a subject becoming infected with such a pathogen, as required by the claimed methods.

Sokal et al. describe a vaginal device (tampon) that contains a flowable preventive formulation, for example, a pharmacological agent. However, Sokal et al. do not teach or suggest that a βCD can be used to reduce the risk of transmission of or infection with a sexually transmitted pathogen and, therefore, do not provide the teaching missing in Bergeron et al. and/or Baert et al. reference. Furthermore, it is submitted that one of ordinary skill in the art would not have been motivated to combine Bergeron et al. and/or Baert et al. with Sokal et al. because, prior to Applicant's disclosure, it was not known that a βCD can reduce the risk of transmission of or infection with a sexually transmitted pathogen, or, therefore, that a βCD was an "active ingredient" useful in a composition as described by Sokal et al.

For the above reasons, it is submitted that the cited references, either alone or in combination, do not teach or suggest that βCD is active in reducing the risk of transmission of or

infection with a sexually transmitted pathogen. As such, it is submitted that the cited references would not have rendered the claimed methods obvious to one of ordinary skill in the art.

With respect to the composition claims, Bergeron et al., Baert et al., and Sokal et al. are provided for the teachings described above, and Baert et al. also is provided as describing a ratio of a cyclodextrin to an active ingredient of 1/100 to 100/1. It is stated in the Office Action that such a range as referred to by Baert et al. encompasses a composition comprising concentrations of βCD encompassed within the claims and, therefore, is alleged it would have been obvious to use βCD in the amounts described because Baert et al. describe pharmaceutical compositions containing these amounts for treating HIV-infected patients, and to make compositions encompassed within the claims because Bergeron et al. describes the inclusion of a film-forming component in their compositions, and because gloves and condoms, for example, are basically films and well known in the art for preventing sexually transmitted disease. It is further stated that it would have been obvious to incorporate the compositions into a tampon or sponge because Sokal et al. describe incorporating pharmacological agents into vaginal devices for preventing the transmission of sexually transmitted diseases.

As discussed above , however, neither Bergeron et al. nor Baert et al. teaches or suggests that βCD can be used as an "active agent", and Sokal et al. do not teach or suggest a cyclodextrin at all. As such, one of ordinary skill in the art would not have known that a βCD has an activity in and of itself and, therefore, would not have been motivated to make a composition "consisting essentially of" a βCD. Accordingly, it is respectfully requested that the rejection of the composition claims under 35 U.S.C. § 103(a) be removed..

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: March 21, 2003

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Enclosure: Exhibit A

EXHIBIT A

MARKED VERSION OF CLAIMS SHOWING THE AMENDMENTS

1. (Twice amended) A method of reducing the risk of transmission of a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a composition consisting essentially of a β-cyclodextrin, wherein said β-cyclodextrin reduces the risk of transmission of the pathogen.

9. (Twice amended) A method of reducing the risk of a subject becoming infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen in the subject with an effective amount of a pharmaceutical composition consisting essentially of a β-cyclodextrin, wherein said β-cyclodextrin reduces [thereby reducing] the risk of the subject becoming infected with the sexually transmitted pathogen.

23. (Twice amended) A method of reducing the risk of transmission of a sexually transmitted disease by a subject infected with a sexually transmitted pathogen, the method comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a pharmaceutical composition consisting essentially of a β-cyclodextrin, wherein said β-cyclodextrin reduces [thereby reducing] the risk of transmission of the sexually transmitted disease by the subject.

37. (Twice amended) A pharmaceutical composition consisting essentially of a β-cyclodextrin and, optionally, an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof.

40. (Twice amended) A composition for reducing the risk of transmission of a sexually transmitted disease, the composition consisting essentially of a β-cyclodextrin, a solid substrate and, optionally, an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof [a β-cyclodextrin].